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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,170	08/30/2000	Robert Eric Montgomery	12080-4	2711

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EXAMINER
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KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/651,170

Applicant(s)

MONTGOMERY ET AL.

Examiner

Frederick F. Krass

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6,14 and 25-43 is/are pending in the application.
- 4a) Of the above claim(s) 6,14,27,28,31,34,35,38,41 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25,26,29,30,32,33,36,37,39,40 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9-17-03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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#### **Claim Informalities**

The following informality is noted and should be corrected to place the claims in better form:

Claim 39, third line, "wit" should be changed to --- with ---

#### **Election of Species Requirement**

Applicant's election (6/30/04) of the compound "EDTA" as the ultimate species of metal ion chelator is noted. Because applicant did not distinctly and specifically point out the supposed errors in the examiner's requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 6, 14, 27, 28, 38, 31, 34, 35, 38, 41 and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species.

#### **Anticipation Rejection**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 26, 29, 32, 33 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Thaler (USP 5,084,268).

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The prior art discloses tooth whitening compositions ("systems") comprising two parts prior to final mixing, one part containing hydrogen peroxide and the other not. See the passage spanning col. 1, line 48 to col. 2, line 8, and col. 3, lines 47-52. The part not containing hydrogen peroxide contains the chelating agent EDTA. See col. 3, lines 8-11 and line 21 in the Table. It also contains water and the "pH-adjusting" agent carbopol (an acidic component). See line 22 in the Table. The final concentration of hydrogen peroxide is 3 percent. See col. 5, lines 16 and 17. The prior art thus meets all the limitations of the instantly rejected claims. The functional limitations of the instant claims (e.g. "capable of activating tooth whitening when in contact with indigenous metal ions in the mouth" in claim 25, and "capable of absorbing light of wavelengths from about 350nm to about 700nm" in claim 32) merely recite inherent characteristics of EDTA (and the other claimed metal ion chelators) and furthermore relate only to future intended use, and thus carry no weight in determining patentability.

### **Obviousness Rejection**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25, 26, 29, 30, 32, 33, 36, 37, 39, 40 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer (USP 5,985,249) in view of Pellico (USP 5,928,628).

The primary reference discloses aqueous tooth bleaching gels ("systems") containing about 3 to about 30 percent hydrogen peroxide (col. 8, lines 38-56), alkaline pH adjusting agents such as sodium hydroxide (col. 8, lines 19-37), and stabilizers comprising chelating agents such as EDTA (col. 9, lines 38-45; see also col. 13, line 22 in working example 1).

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As discussed in the "Anticipation" section above, the functional limitations of instant claims 25 and 32 merely describe characteristics inherently possessed by EDTA. The requirement of instant claim 39 that the first and second components be "sufficiently transparent to light" to permit light from dental activating lamps "be applied to a tooth surface bearing the first and the second part" is also merely a requirement that the claimed compositions be "capable" of a particular future function, and thus carries no weight in determining patentability. Furthermore, the gels of the primary reference contain no abrasives, pigments, or other components which would be expected to impart opaqueness. Accordingly, the prior art gels would appear to be sufficiently transparent to permit light from dental activating lamps to reach the tooth surface during bleaching. (And in any case, the construction of instant claim 39 does not even require this level of transparency; it merely requires that light "can be applied" to the tooth surface. Almost any gel not completely opaque would permit at least some light to be "applied").

The primary reference differs from the instant claims insofar as it discloses one-part gels, not two-part compositions are required instantly. The secondary reference teaches, however, that the bleaching activity of aqueous dental bleaching gels can be substantially increased by preparing them in two-part form, the first part having a pH of about 4 to about 7 and containing the peroxide bleaching agent, and the second part having a pH of about 9 to about 13 and containing other components which would prematurely activate the peroxide, e.g. bases such as sodium hydroxide. See for example col. 3, lines 27-38 and col. 5, lines 8-16. The secondary reference differs from the instant claims insofar as it is silent regarding metal ion chelators.

It would have been obvious to have prepared the dental bleaching gels of the primary reference in two-part form, the first part having an acidic pH and containing hydrogen peroxide, the second part having an alkaline pH and containing potentially reactive components, e.g. EDTA, motivated by the desire to increase performance (bleaching activity) as taught by the secondary reference.

**C rresp ndence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;  
Tuesday: 10:30AM - 7PM;  
Wednesday: off;  
Thursday: 10:30AM- 7PM; and  
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
Art Unit 1614

